

REMARKS

Claims 1-9, 11-23, 25 and 27 are pending. By virtue of this response, claims 11-14 are amended. Claims 2, 9, and 25 are withdrawn. Therefore, claims 1, 3-8, 11-23, and 27 are presently under examination. Amendment and cancellation of certain claims is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter was added by this amendment.

I. Claim Objections

Claims 13-23 are objected to because of the following informalities: the claims are objected to as depending from non-elected subject matter.

Applicants have amended claims 12-14 to remove the dependency from withdrawn claim 2.

Applicants therefore respectfully request that the Examiner withdraw the objection to the claims.

II. Double Patenting

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1-33 of copending Application No. 12/351,281.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 24-44 of copending Application No. 12/321,464.

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 34 and 67 of copending Application No. 12/321,420.

Applicants respectfully request that the Examiner hold these three rejections in abeyance until such time as there is an indication of otherwise allowable subject matter. Only at that time will Applicants be able to determine whether an obviousness-type double patenting rejection is

applicable given that the claims may be further amended during prosecution and withdrawal of a terminal disclaimer is highly disfavored.

Applicants further note that even if the provisional rejections are valid, if the only rejection pending in an earlier filed application such as the present application is such a provisional rejection and the later filed applications are still subject to other rejections, that the Examiner should withdraw the provisional rejections and allow the earlier filed application to issue. See MPEP 804(I)(B)(1). Thus, if this amendment and response overcomes all other pending rejection, the Applicants respectfully request that this provisional rejection be withdrawn and the application proceed to allowance.

III. Claim Rejection Under 35 USC §102 – WO03/007985

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are rejected under 35 U.S.C. 102(b) as allegedly being anticipated by WO 03/007985 published 30 January 2003.

Applicants respectfully traverse the rejection and its supporting remarks. WO03/007985 fails to anticipate the pending claims as it fails to teach either expressly or inherently that the saccharides have “between 2-9% of the sialic acid residues in the saccharide are O-acetylated at the 7 position” and/or “between 35-55% of the sialic acid residues in the saccharide are O-acetylated at the 9 position”. The Examiner has acknowledged that WO03/007985 fails to expressly disclose either claim limitation. The Examiner instead appears to be asserting that WO03/007985 inherently discloses capsular saccharides that meet these limitations based upon the assertion that “As the instantly claimed conjugates are made by the identical process as the prior art, the compositions of the prior art necessarily have the recited structures present and uses the same strain W135 see data at pages 20 and 27.” Applicants respectfully disagree with the Examiner’s assertion and characterization of the teachings of WO03/007985. First, the two pages of WO03/007985 cited by the Examiner for allegedly teaching that the capsular saccharides were obtained from MenW135 5554 is a mis-reading of the two tables. Page 19, lines 10-15 of WO03/007985 teaches that the tables show the bactericidal activity of the against two MenW135 test strains. MenW135 5554 was selected because it was an O-acetylation positive strain (OAc+) and MenW135 242317 was selected because it was an O-acetylation negative strain (OAc-). Thus, this section clearly teaches that there

are MenW strains that have O-acetylation and MenW strains that do not have O-acetylation. Thus, WO03/007985 does not teach the strain of MenW that was used to generate the capsular saccharide. Since WO03/007985 does not teach which strain was used in the protocols on pages 16-17, WO03/007985 does not *necessarily* teach MenW compositions that inherently would meet the limitations of the pending claims. MPEP 2112(IV) sets out the requirements for inherent anticipation as:

The fact that a certain result or characteristic *may* occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). “To establish inherency, the extrinsic evidence ‘must make clear that the missing descriptive matter is *necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, *may not be established by probabilities or possibilities*. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.’” *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ...

If one of skill in the art used the methods of WO03/007985 on an OAc- strain, the resulting capsular saccharides would likely not meet the limitations of the claim. Therefore, based upon starting materials alone, WO03/007985 does not inherently anticipate the pending claims. The burden to establish inherency is clearly on the Examiner. The Examiner cannot merely assert that inherency is found absent evidence to the contrary. Thus, unless the Examiner can provide evidence or sound reasoning that WO03/007985 *necessarily* teaches capsular saccharides meeting the limitations of the claims, the Examiner has not established that WO03/007985 inherently anticipates the claimed invention.

Moreover, the Examiner has asserted that the present application does not cite to the “criticality of any W135 strain,” but no one strain or set of strains is critical to the presently claimed invention. Applicants respectfully assert that the claims do not recite any strains or starting strains as the starting strain is only relevant if one of skill in the art wants to use the exact protocol in the

specification without alteration. However, one of skill in the art will be aware of a number of methods in the art for altering the degree of OAc of the saccharides, which can be used at any step during any standard protocols to ensure that the resulting compositions have the claimed degree of acetylation. Thus the choice of starting strains is not relevant to one of skill in the art practicing the claimed invention. The starting strain is only relevant for WO03/007985 as the starting strain affects the resulting composition taught in WO03/007985. Since WO03/007985 does not *necessarily* teach a composition within the scope of the pending claims, WO03/007985 does not inherently anticipate the pending claims.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1, 3-8, 11-13 and 14-18 and 20-23.

IV. Claim Rejection Under 35 USC §102 - Costantino

Claims 1, 3-8, 11-13 and 14-18 and 20-23 are rejected under 35 U.S.C. 102(e) as allegedly being anticipated by Costantino (U.S. Publication No. 2009/0117148) or Costantino U.S. Publication No. 2009/0182129) or Costantino (U.S. Publication No. 2009/0130147) or Costantino (U.S. Publication No. 2005/0106181).

Applicants respectfully traverse the rejection and its supporting remarks. U.S. Publication No. 2005/0106181 is the US national stage of WO03/007985 discussed above, and each of U.S. Publication No. 2009/0117148; U.S. Publication No. 2009/0182129; and U.S. Publication No. 2009/0130147 claim priority to U.S. Publication No. 2005/0106181 as continuations or divisionals thereto. The Examiner has not cited to any alleged differences in the disclosures of these US patent publications compared to WO 03/007985. Therefore, as discussed above regarding WO03/007985, all of the cited patent applications also fail to anticipate the pending claims as each fails to teach either expressly or inherently that the saccharides have “between 2-9% of the sialic acid residues in the saccharide are O-acetylated at the 7 position” and/or “between 35-55% of the sialic acid residues in the saccharide are O-acetylated at the 9 position”.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1, 3-8, 11-13 and 14-18 and 20-23.

V. Claim Rejection Under 35 USC §103

Claim 19 is rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over WO 03/007985 published 30 January 2003 in view of WO 03/080678, published October 2, 2003, filed March 23, 2003).

Applicants respectfully traverse the rejection and its supporting remarks. As discussed above, WO03/007985 fails to teach or suggest either expressly or inherently that the saccharides have “between 2-9% of the sialic acid residues in the saccharide are O-acetylated at the 7 position” and/or “between 35-55% of the sialic acid residues in the saccharide are O-acetylated at the 9 position” for the reasons discussed in Section III, above. Therefore, the Examiner has not established a *prima facie* case of obviousness.

Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 1, 3-8, 11-13 and 14-18 and 20-23.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **Docket No. 223002121500**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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